

REMARKS/ARGUMENTS

Claims 1-11 and 13-20 have been withdrawn from consideration in view of the restriction requirement and claims 12 and 21-26 have been examined. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Claim 12 has been cancelled, and new claims 27-33 have been added. Claims 21-26 have been amended. No new matter has been added. Support for the amendments may be found throughout the specification, including the claims as originally filed. For example, support for certain of the new claims may be found on page 12. Amendment of claims should in no way be construed to narrow their scope or as an acquiescence to any of the Examiner's rejections. The amendments to the claims are being made solely to expedite prosecution of the present application.

An abstract has been added, as requested by the Examiner.

Rejection of claims 12 and 21-26 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 12 and 21-26 under 35 U.S.C. § 112, second paragraph as being allegedly indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner has asserted that it is not clear in claim 12 what is meant by “SYNIP,” because the definition of “SYNIP” at page 12 is so broad as to be meaningless. The Examiner urges that this is so because there is no definite structure and no definite function set forth for this term.

Applicants have cancelled claim 12, and have amended claim 21 to recite that a “SYNIP” as claimed must have an amino acid sequence substantially similar to the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5. The term “substantially similar” is defined at page 8 of the specification as follows: “‘substantially similar’ includes identical sequences, as well as deletions, substitutions or additions to a DNA, RNA or protein sequence that maintain the function of the protein product and possess similar zinc-binding motifs.” The definition of “SYNIP” at page 12 notes that such functional derivatives and variants must share some degree of homology with or mimic the structure of a native SYNIP, such as a SYNIP having SEQ ID NO: 2 or SEQ ID NO: 5. Thus a definite structure is set forth by this definition. Accordingly, Applicants urge that the term “SYNIP” as used within the claims is not indefinite.

Further, the Examiner has asserted that claim 12 is not clear because “syntaxin-4” is defined as including but not limited to syntaxin-4 “and the like.” Applicants, in order to clarify this term for the purposes of advancing the prosecution of this application, submit that “syntaxin-4” as used in the present claims is limited to syntaxin-4. Accordingly, Applicants urge that the term “syntaxin-4” is not indefinite.

The Examiner has also asserted that it is not clear in claim 12 what is meant by the phrase “interferes with the interaction,” in that it is not clear how a compound interferes with an interaction between SYNIP and syntaxin-4 such as binding, affecting, or regulating. Applicants have amended the claims to recite “block the binding”.

Support for this amendment may be found, for example, page 16, line 3. Accordingly, this rejection has been rendered moot.

Finally, the Examiner has indicated it is not clear what the term “substantially similar” means when used to compare sequences as in claims 21, 23, and 24. As noted above, this term is defined at page 8 of the specification as follows: “‘substantially similar’ includes identical sequences, as well as deletions, substitutions or additions to a DNA, RNA or protein sequence that maintain the function of the protein product and possess similar zinc-binding motifs.” Accordingly, Applicants assert that the term “substantially similar” is clearly defined in the specification and is therefore not indefinite.

In light of the foregoing arguments, Applicants respectfully request the withdrawal of the all of the rejections under 35 U.S.C. § 112, second paragraph for indefiniteness.

Rejection of claims 12 and 21-26 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claim 6 under 35 U.S.C. § 112, first paragraph as allegedly lacking written description of the invention as claimed.

First, the Examiner has indicated that “SYNIP”s are not described as defined on page 12. Specifically, the Examiner notes that the specification does not describe functional derivatives and variants that are included in the definition of “SYNIP.” Applicants have cancelled claim 12, and have amended claim 21 to recite that a “SYNIP” as claimed must have an amino acid sequence substantially similar to the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. The recent revised Written Description Guidelines (66 FR 1099) indicate that “The written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* . . . or by . . .

functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus” (pg 1106, column 3, *Fed. Reg.* Vol 66, No. 5 Friday January 5, 2001). Applicants have reduced to practice two different naturally-occurring SYNIP sequences, SEQ ID NOs: 2 and 5 as described at pp. 11, 24, and 36. Further, Applicants have disclosed the function of such sequences. The definition at page 12 also provides that “functional derivatives and variants” of SYNIPs are any compounds having a qualitative biological activity in common with a native SYNIP, whose function is disclosed at page 2. The definition at page 12 further notes that such functional derivatives and variants must share some degree of homology with or mimic the structure of a native SYNIP. Because Applicants have thereby disclosed a function, several structures and a correlation between them, Applicants urge that the written description requirement has been met for claim 21 as amended, as well as claims that depend from claim 21.

Further, the Examiner has indicated “syntaxin-4-like compounds” are not described. Applicants, in order to clarify this term, submit that “syntaxin-4” as used in the claims is limited to syntaxin-4. The specification describes the syntaxin-4 molecule, as well as its functional characteristics on pages 1-2. Further, the specification on pages 11, 18-19, and 28-30 discloses assays for detecting SYNIP interactions and compounds involved therein. Accordingly, one of skill in the art, considering the functional and structural knowledge about syntaxin-4 as well as the methods for finding similar compounds disclosed in the specification, would recognize that Applicants had possession of the claimed invention. Thus, the written description requirement has been met.

The Examiner has also indicated that the specification does not describe any compound or molecule that “interferes with the interaction” of SYNIP and syntaxin-4. Applicants have amended the claims to recite “block the binding”. An example of a molecule that blocks the binding between SYNIP and syntaxin-4 is insulin, described in the specification at pages 30-32. Accordingly, this rejection has been rendered moot.

Finally, the Examiner has indicated that the specification does not teach polypeptides that are “substantially similar” to SEQ ID NO: 2 or SEQ ID NO:5 and having function. Again, Applicants respectfully direct the Examiner’s attention to the recent revised Written Description Guidelines (66 FR 1099), which state “The written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* . . . sufficient to show the applicant was in possession of the claimed genus” (pg 1106, column 3, *Fed. Reg.* Vol 66. No. 5 Friday January 5, 2001). Further, the guidelines state that “A ‘representative number of species’ means that the species which are adequately described are representative of the entire genus” and that “satisfactory disclosure of a ‘representative number’ depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” (*Id.*) Applicants respectfully contend that the disclosure of the species SEQ ID NOS. 2 and 5 are sufficient to meet the written description for a polypeptide that is “substantially similar” to SEQ ID NO: 2 or SEQ ID NO:5. SEQ ID NO: 2 is an example of a SYNIP that is “substantially similar” to SEQ ID NO: 5., and SEQ ID NO: 5 is an example of a SYNIP that is “substantially similar” to SEQ ID NO:2, because each sequence represents a functional variant of the other. The definition of “substantially similar” includes sequences that are variants of either SEQ ID NO 2 or 5. Accordingly, because a representative number of such species are disclosed in the specification and the term “substantially similar” is defined, one of skill in the art could determine what other polypeptides were “substantially similar” to a “SYNIP having an amino acid sequence substantially similar to the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5.” Therefore, Applicants believe the written description requirement has been met.

In light of the foregoing arguments, Applicants respectfully request the withdrawal of the all of the rejections under 35 U.S.C. § 112, first paragraph for lack of written description.

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000. No fee is believed to be due in connection with this application. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this application be charged to Deposit Account, No. 06-1448.

Respectfully submitted,

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